

QUALITY ASSURANCE ANNUAL REPORT AND WORK PLAN

QUALITY STAFF

FY 2003/2004

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November 2003

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1. QUALITY MANAGEMENT RESOURCES

1.1 Personnel Resources

	FTE	
	Actual FY2003	Projected FY2004
Organization's total filled FTE positions:	16.0	13.0
EPA (and other Federal) FTE involved in the management of QA and QC activities:	12.0	10.0
EPA (and other Federal) FTE involved in QA and QC technical support activities:	2.0	2.0
EPA FTE involved in other non-technical QA and QC support activities:	2.0	1.0
Contractor FTE involved in QA and QC support activities:	4.7	4.7

1.2 Financial Resources

	Estimates (\$K)	
	Actual – FY2003	Projected – FY2004
Extramural Resources (not including travel funds or training):	880	865
Travel oversight, surveillance, and audits/assessments:	96.1	96.1
Training (including registration fees) and travel for training:	15	30

1.3 Adequacy of Resources

The Quality Staff began Fiscal Year 2003 with one vacancy corresponding to the retirement of a senior staff person. Three additional senior staff members will retire by January 8, 2004. We are hopeful that discussions related to the critical need to backfill these vacancies will prove to be fruitful, but there is no guarantee. At full strength, the resources allocated to the work of the Quality Staff are not optimal, and this year a serious shortfall of four (4) FTE will exacerbate the situation, at least temporarily. Historically, the work of the Quality Staff has been interrupted by higher priorities (eg: laboratory fraud), and adjustments have been made to meet these agency wide challenges. The looming 25% reduction in FTE will make it extremely difficult to meet the core responsibilities for oversight, training, guidance, and assessment needs of the Agency in a timely manner.

2. TRAINING

2.1 Needs Assessment

Needs of Quality Staff Members. The training needs of the Quality Staff were developed by the individual staff members and documented in their mandatory Individual Development Plans (IDPs). Staff members then search out the training they need and schedule it to fit into their work load.

Agency QA Training Needs. A needs assessment survey was conducted in September 2003. The results were evaluated and work began on developing courses to address the topics identified through the assessment. We anticipate the development of a training plan in mid FY 2004 based on these assessments.

2.2 QA and QC Courses Provided and Taken

QA and QC Courses Provided by Organization		
Course Title (Supplier = Quality Staff)	# Attendees	
	from Org.	from Other Orgs. (identify)
Courses given at the Annual Meeting in New Orleans, April 2003		
Overview of Quality System Requirements	0	20 trained. From EPA (NPO, ORD, RO) other Fed, state, private sector
Intro to Data Quality Objectives	0	23 Trained. From EPA (NPO, ORD, RO) other Fed, state, private sector

QA and QC Courses Provided by Organization		
Course Title (Supplier = Quality Staff)	# Attendees	
	from Org.	from Other Orgs. (identify)
Assessing Quality Systems	0	41 Trained. From EPA (NPO, ORD, RO) other Fed, state, private sector
Introduction to QA Project Plans	0	35 Trained. From EPA (NPO, ORD, RO) other Fed, state, private sector
Environmental Data Verification and Validation	0	55 Trained. From EPA (NPO, ORD, RO) other Fed, state, private sector
Environmental Data Verification and Validation	0	45 Trained. From EPA (NPO, ORD, RO) other Fed, state, private sector
Understanding Environmental Multivariate Data	0	23 Trained. From EPA (NPO, ORD, RO) other Fed, state, private sector
Courses given at the Annual Training Conference in Atlanta, September 2003		
Overview of Data Quality Indicators	0	36 Trained. From EPA (NPO, ORD, RO) other Fed, state, private sector
Planning For and Interpreting Environmental Data	0	43 Trained. From EPA (NPO, ORD, RO) other Fed, state, private sector
Introduction to Data Quality Objectives	0	27 Trained. From EPA (NPO, ORD, RO) other Fed, state, private sector
Introduction to Data Quality Assessment	0	62 Trained. From EPA (NPO, ORD, RO) other Fed, state, private sector
Introduction to QA Project Plans	0	40 Trained. From EPA (NPO, ORD, RO) other Fed, state, private sector
Overview of Quality Management Plans	0	16 Trained. From EPA (NPO, ORD, RO) other Fed, state, private sector
EPA Quality System Requirements Overview	0	30 Trained. From EPA (NPO, ORD, RO) other Fed, state, private sector
Assessing Quality Systems	0	35 Trained. From EPA (NPO, ORD, RO) other Fed, state, private sector
Environmental Data Verification and Validation Description	0	45 Trained. From EPA (NPO, ORD, RO) other Fed, state, private sector

QA and QC Courses Provided by Organization		
Course Title (Supplier = Quality Staff)	# Attendees	
	from Org.	from Other Orgs. (identify)
Understanding Environmental Multivariate Data	0	33 Trained. From EPA (NPO, ORD, RO) other Fed, state, private sector
Information Quality Guidelines	0	2 Trained. From EPA (NPO, ORD, RO) other Fed, state, private sector
Courses given at various times throughout 2003		
Introduction to Modeling QA Project Plans	0	21 trained in Region 1, 18 trained in Region 6 (Fed, state)
Quality Requirements for Grants and IAGs (a module in the Grants PO training course)	0	c. 112 EPA employees trained. Course given approximately every quarter.
Data Quality Assessment	0	28 OSWER Emergency Response People trained
Statistical QA	0	35 trained from Quality Staff of the State of Nevada
Statistical QA	0	20 trained from USGS-DODEC
"Writing and Developing QA Project Plans"	0	c. 45 Region 3 Remedial PMs, OSCs, state personnel, and contractors

QA and QC Courses Taken by Organization		
Course Title	Supplier	# Attendees (from Org.)
OGC training on non-binding guidance	OGC	c. 10
Intro to JAVA	USDA	1
Javascript Programming	USDA	1
Acrobat Accessibility Trining	Alpha Gamma	3
"Leadership, Ethics, Integrity, and Public Service"	Brookings/IRS	1

QA and QC Courses Taken by Organization		
Course Title	Supplier	# Attendees (from Org.)
Workshop on PCR (polymerase chain reaction)	American Society for Microbiology	1

2.3 Other Training Information

Both the PowerPoint and the HTML versions of core QA courses were added to the Quality System Website. Previously only the Freelance Versions were available.

At present, the Quality Staff has developed with 18 courses. Of these, 8 have been posted on the web, 6 are final but not yet on the web, and 4 have been piloted but are still under development.

Posted on the Quality System Web site in 2003:

- Detecting Improper Laboratory Practices – Finalized
- Introduction to Data Quality Assessment – Finalized
- Introduction to Data Quality Indicators – Finalized
- Introduction to Quality Assurance Project Plans – Revised

Finalized

- Data Validation/Verification

Final steps of development:

- Analyzing Monitoring Data
- Censored Data and Detection Limits
- Interpreting Multivariate Data
- Sampling Designs to Support QA Project Plans
- Introduction to Modeling QA Project Plans
- Assessing Quality Systems
- Introduction to QA Project Plans for Modeling
- Introduction to Geospatial Data QA Project Plans
- Statistical Concepts for QA Practitioners.

In 2003, the Quality Staff was certified as International Association for Continuing Education and Training (IACET) authorized providers. As an authorized provider, the Quality Staff awards the IACET Continuing Education Unit (CEU) for more than 60% of its training courses. This certification demonstrates that the Quality Staff training curriculum is compliant with proven, research-based criteria supported by the U.S. Department of Education and dedicated to high

standards in continuing education and training for the EPA Quality Community. CEU records are maintained for 7 years by the Quality Staff and are available upon request by training participants. To maintain these records, the Quality Staff developed a database for tracking Continuing Education Units (CEUs).

3. QUALITY SYSTEM-RELATED ACCOMPLISHMENTS

3.1 Innovative Practices

The Quality Staff developed detailed Operating Plans based on the goals identified in the 2001 Quality Staff Strategic Plan. These strategic goals are:

- Documenting Quality System Policies and Procedures
- Managing Change
- Improving Outreach to and Collaboration with the Environmental Community.
- Communicating the Message
- Meeting the Agency's QA Training Needs
- Assessing Quality Management Systems
- Improving Organizational Strength in the Quality Staff

(Note: two of the goals were combined into a single operating plan.) Each Operating Plan contains a description of the activities needed to accomplish the goal, performance measures, corrective actions, and tracking procedures. Each Operating Plan also identifies Standard Operating Procedures that are available or are needed to accomplish the goal. The Operating Plans were updated for FY 2003. The Quality Staff also developed Work Plans to support each Operating Plan. Work Plans identify tasks or activities for the fiscal year with estimated resource requirements.

The Quality Staff updated the template for QA Annual Reports and Work Plans to provide requested clarification on certain elements.

3.2 Revisions to Quality Management Plan

Not Applicable. The Quality Staff's roles and responsibilities are defined in EPA Order 5360.1.

3.3 Technical Assessments

Technical Assessments			
Type	Org./ Project Assessed	Assessor (and Org.)	Date(s)
Technical Systems Audit	National Enforcement Investigations Center, (NEIC) Denver	OECA with Fred Siegelman of the Quality Staff	May 2003
Quality and Technical System Assessment	OPPTS Microbiology Laboratory	Betsy Grim, OPPTS, with Margo Hunt of the Quality Staff	Feb 2003

Furthermore, a capping report summarizing the FY01-02 Technical Systems Assessments of Office of Research and Development and National Program Office laboratories was submitted to the Deputy Administrator.

3.4 Technical Assistance

Quality Management Plans		
<i>Organization</i>	<i>Status</i>	<i>Date Approved</i>
Office of International Activities (OIA)	Approved	25 Oct 2002
Region 8	Approved	13 Dec 2002
Office of Atmospheric Programs (OAR)	Approved	23 Jan 2003
Region 9	Approved	12 Mar 2003
Great Lakes National Program Office (GLNPO)	Approved	28 Apr 2003
Office of Science Coordination and Policy (OPPTS)	Approved	6 June 2003
Region 10	Approved	16 June 2003
Region 4	Approved	24 June 2003
Region 3	Approved	7 July 2003
Office of Compliance (OECA)	Approved	30 July 2003
Office of Pollution Prevention and Toxics (OPPTS)	Approved	30 July 2003

Quality Management Plans		
<i>Organization</i>	<i>Status</i>	<i>Date Approved</i>
National Homeland Security Research Center (ORD)	Approved	21 Aug 2003
Office of Solid Waste and Emergency Response (OSWER)	Approved	11 Sept 2003

Other Technical Assistance	
<i>Organization</i>	<i>Type of Assistance</i>
OECA	Assisted intern with white paper on Information Quality Guidelines and Quality System
OEI	Customer Profile
NRMRL	Reviewed QAPP for Statistical Software
Region 7	Reviewed statistical portion of QAPP
Region 9	Statistical analysis support
QA Community	Revised HQ conference calls to meet needs of participants
QA Community	Approximately 12 instances of statistical assistance
QA Community	Updated Community list and Lotus Notes groups
HQ QAMS	Developed discussion database
Various	Email requests to <i>quality@epa.gov</i> : Responded to 178 requests for assistance. Added 250 individuals to notification list.
FBI	Review of “QA Guidelines for Laboratories Performing Microbial Forensic Work”
OPPTS	Review of draft QA Project Plan for Plant Protectant Program

3.5 QA Guidance

3.5.1 Survey of Guidance Needs

The Quality Staff conducted a survey in April 2003 to assess the Agency’s needs for QA guidance. The top three areas of need were Assessments, Statistics, and Laboratory Data Quality. A large fraction of respondents also favored: 1) abbreviated versions of existing guidance; 2) case studies; and, 3) program specific examples. The results will be used to direct future guidance document development.

3.5.2 QA Guidance Issued

- Overview of the EPA Quality System – Nov 2002
- Guidance on Environmental Data Verification and Validation – Nov 2002
- Developing a Quality System – Nov 2002
- Guidance on Choosing a Sampling Design for Environmental Data Collection – Dec 2002
- Guidance for Quality Assurance Project Plans for Modeling – Dec 2002
- Guidance for Quality Assurance Project Plans (5-year Update) – Dec 2002
- Guidance on Assessing Quality Systems – March 2003
- Guidance on Geospatial Quality Assurance Project Plans – March 2003

3.5.3 QA Guidance Development Completed

- Guidance on Data Quality Indicators

3.5.4 QA Guidance Peer Reviewed

- Guidance on Quality Assurance for Environmental Technology Design, Construction, and Operation

3.5.5 QA Development Initiated

- Guidance on Systematic Planning for Environmental Projects, (5-year update)
- Guidance on Data Quality Objectives, (5-year update)
- Integrating Systematic Planning and QA Project Plans
- Data Quality Assessment: An Overview
- Data Quality Assessment: Statistical Techniques
- Statistical Case Study: Monitoring
- Statistical Case Study: Multiple Decision Making.

3.6 Publications and Presentations

- “EPA’s Quality System and Staff,” Office of Water Annual Quality Assurance refresher training. September 2003, Margo Hunt
- “EPA’s Approach to QA for Modeling” was presented to OPPT in early FY03, Linda Kirkland
- “Quality and Project Management,” presented to the Office of the Chief Information Officer, Agricultural Research Service, Beltsville, MD, August 2003, Nancy Wentworth
- “Quality Systems at the Environmental Protection Agency,” presented to US Food and Drug Administration national video conference, Quality Systems and Risk-Based Regulatory Approaches, Rockville, MD, October, 2003, Nancy Wentworth
- “Restructuring the National Environmental Laboratory Accreditation Conference,”

- for the National Cooperation for Laboratory Accreditation, March 2003, Columbia, MD, Nancy Wentworth
- “Update on Quality Staff Activities,” National meeting in New Orleans, 4/03, Nancy Wentworth
- “What A Quality Assurance Manager Needs to Know about the Information Quality Guidelines,” presented as part of the 12/02 Quality Staff training sessions in Ballston, Nancy Wentworth
- “Update on Quality Staff Activities”, American Council of Independent Laboratories, Feb, 2003, Washington, DC Nancy Wentworth
- “Science and Data, How do we know that we have the right data, right, for our decisions?” Air Force Center for Environmental Excellence Technology Conference, San Antonio, TX, Feb 2003, Nancy Wentworth
- “Update on EPA’s Quality Activities”, 30th National Energy and Environment Conference, Las Vegas, NV, Sept 03, Wentworth
- “EMS Self-Declaration Versus Certification: Benefits and Myths.” ASQ ISO 9000/ISO 14000 Conference, Dallas, Texas, March 2003, Gary Johnson
- “QE 19011S - the U.S. Supplement to ISO 19011,” with John Stratton (Consultant). ASQ ISO 9000/ISO 14000 Conference, Dallas, Texas, March 2003, Gary Johnson
- “Introducing QA/G-11: EPA’s New Guidance on QA for Environmental Technology,” with Kevin Hull (Neptune and Company) and Joseph Evans (SAIC). EPA National Quality Management Conference, New Orleans, Louisiana, April 2003, Gary Johnson
- “Conducting Internal QMS Audits.” EPA National Quality Management Conference, New Orleans, Louisiana, April 2003, Gary Johnson
- “Combined QMS-EMS Auditing Using ISO 19011 and QE 19011S,” with Mary McDonald (ISO/QS, Inc.). ASQ Energy and Environmental Division National Conference, Las Vegas, Nevada, September 2003, Gary Johnson

3.7 Awards and Recognition

3.7.1 Bronze Medals.

Lisa Doucet, Fred Siegelman, Pat Lafornera, Esperanza Renard, and Margo Hunt were awarded OEI Bronze Medals for their work in performing Technical Systems Audits of the Agency’s laboratories.

Linda Kirkland was awarded a Bronze Medal for collaboration on the Geospatial Blueprint.

Vincia Holloman was awarded an OEI Bronze Medal for team effort in enhancing OEI’s strategic consolidation of FY02 and FY03 Performance Goals and Measures and developing OEI’s Cross-Cutting Strategy of the EPA FY 03 Strategic Plan.

Vincia Holloman was awarded an OEI Bronze Medal for developing OEI’s chapter of the EPA FY03 Strategic Plan

3.7.2 Other Awards

Gary L. Johnson of the Quality Staff received the *Outstanding Achievement in Standards Development Award* from the U.S. Technical Advisory Group (TAG) to ISO/TC 207 on Environmental Management for his leadership in representing the U.S. position in the development of ISO 19011:2002, *Guidelines for Quality and/or Environmental Management Systems Auditing*. Johnson represented TAG 207 and the American National Standards Institute (ANSI) as one of three U.S. Experts in the development of this new International Standard.

3.8 Other QA Management Accomplishments

NELAC Database. The Quality Staff completed the development of the National Environmental Laboratory Accreditation Conference (NELAC) database and delivered it to the Deputy Assistant Administrator of ORD on a CD. The ORD NELAC director announced its availability and is working with NELAC members to determine the best way to institute and maintain this database.

The Quality Website continues to be a premier source of information on QA. Users from EPA, other federal agencies, State and Local governments, foreign governments, the private sector, academia and members of the general public visit the site and download documents. This year we had 147 requests for information and 254 additions to our email notification list.

Quality System Mapping. The Quality Staff and OEI's Office of Information Acquisition and Analysis (OIAA) are developing a framework paper on quality in the Agency by mapping the different quality-related activities that occur across the Agency. These activities include but are not limited to the Agency's quality System, the Information Quality Guidelines, and the Agency Peer Review System. The initial purpose of this framework paper is to begin discussions with both management and technical staff aimed at identifying all existing policies and procedures that govern quality aspects of Agency products. Once a framework has been agreed upon, the next steps will be to use the framework to identify any gaps in tools for conducting projects and to eliminate any duplicate policies and guidance.

Contracts Management Manual: The Office of Acquisition Management (OAM) released for Directives Clearance the proposed new chapter on QA contained in the Contracts Management Manual (CMM). This chapter is the product of a cross-Agency workgroup led by the Quality Staff. The workgroup was charged with updating the quality system requirements for EPA's solicitations and contracts. The workgroup is developing a website to help QA personnel, Contracting Officer Representatives (WAMs POPOs, etc.) and contracting officers implement the revised procedures for quality in contracts.

Communication: The Quality Staff fostered communication among members of the QA community by maintaining the QA community list and e-mail groups, and by sponsoring three monthly conference calls. We revised the HQ call structure to meet the needs of participants.

Strategic Planning. The Quality Staff participated in the development of Development of OEI/QS FY 2004 Strategic Plan which is part of EPA's FY2003-2008 Strategic Plan.

Work Group Participation: Quality Staff members participated in the following Work Groups:

- ANSI International Forum
- ANSI-RAB National Accreditation Program EMS Council
- ANSI Z1 Accredited Standards Committee on Quality Management, Environmental Management, Dependability, and Statistics
- Accreditation and Certification Board/Registrar Accreditation Board
- Contracts Management Manual Revision Workgroup
- CREM/Model Evaluation Guidance Development
- EMS Office Directors Policy Council
- Environmental Information Management System Development Team
- Environmental Lab Results Data Standard Action Team
- Environmental Measurements eXtensible Mark-up Language (XML) Action Team
- EPA Web Workgroup
- EPA Environmental Management Systems Workgroup
- EPA's Science Advisory Board Implementation Workgroup
- EPA's Science Inventory Implementation Workgroup
- EPA's Small Business Strategy Development and Implementation Workgroup
- FASTAC Workgroup
- FEM Method Validation Team
- FEM Combining Conferences Action Team
- Forum for Environmental Measurements (FEM) Laboratory Competency Action Team
- Grants Customer Relations Council
- Homeland Security Laboratory Capability Workgroup
- Inter Governmental Data Quality Task Force (IDQTF)
- INELA On-Site Assessment Committee
- INELA Quality Systems Committee
- Lab Quality Systems Practices Implementation Plans Workgroup
- Microbiology Subcommittee National Data Base Committee
- National Primary Drinking Water Regulations: Analytical Method for Uranium
- National Primary Drinking Water Regulations: Revisions to the Total Coliform Monitoring and Analytical Requirements and Additional Distribution System Requirements
- National Primary and Secondary Drinking Water Regulations: Approval of Additional Method for the Detection of Coliforms and *E. coli* in Drinking Water
- NELAC On-Site Assessment Committee, Quality System Committee
- NELAC Standards Review Committee
- OEI IT representatives
- OEI Communications Workgroup

- OEI/Geospatial Data Workgroup
- OEI System Life Cycle Management Policy
- OEI Tribal Strategy Workgroup
- OEI's Strategic Planning Workgroup
- OGWDW Drinking Water Certification Manual, Microbiology Committee
- Research and Science Architecture Workgroup for Quality Program Issue
- Revisions to the Unregulated Contaminant Monitoring Regulation for Public Water System; Proposed Rule
- Standard Methods, Part 9000 (microbiology) coordinator
- Statistical Policy Advisory Committee
- U.S. Technical Advisory Group to ISO Technical Committee 176 on Quality Management
- U.S. Technical Advisory Group to ISO Technical Committee 207 on Environmental Management

Quality Staff Administrative Procedures. The Quality Staff developed and/or updated SOPs for:

- Steps for Issuing Products (including Quality System Series Guidance)
- Procedure for Finalizing Documents – updated
- Procedure for 5-year Updates of Existing QA Guidance Documents.

4. ASSESSMENTS OF QUALITY SYSTEMS

Quality System Assessments		
Quality System Assessed	Assessor (Quality Staff)	Date(s)
National Health and Ecological Research Lab (ORD)	Margo Hunt	4/22/03 - 6/19/03
Office of Ground Water and Drinking Water (OW)	Linda Kirkland	7/15/03 - 7/17/03
Office of Information analysis and Access (OEI)	James Stemmler	6/18/03 - 6/20/03
Office of Solid Waste (OSWER)	Gary Johnson	4/8/03 - 4/10/03
Region 6	Gary Johnson	6/23/03 - 6/27/03
Office of Air Quality Planning and Standards (OAR)	Pat Lafornera	4/28/03 - 5/1/03
Office of Children's Health Protection (OA)	Margot Hunt	2/2/03 - 2/5/03
Office of Environmental Justice (OECA)	Diann Sims	5/31/03
Region 2	Pat Lafornera	3/10/03 - 3/14/03

5. PLANNED ACTIVITIES

5.1 Training

5.1.1 *Planned Events*

- Annual Quality Systems Training Conference: October 2004, with multiple offerings of courses from the Quality Systems Training curriculum.
- 23rd National Conference on Managing Environmental Quality Systems: April 2004, with multiple offerings of courses from the Quality Systems Training curriculum.
- Quality Assurance - Grants Project Officer Training: On-going Support throughout the year.
- OSC Readiness Conference – Presentation of “Sampling Designs”, 21 Nov 2003.
- European Conference on Quality and Methodology in Official Statistics, 24 May 2004
- Use of Secondary Data Within EPA’s Quality System to be presented by Quality Staff to OCHP/OPEI.

5.1.2 *Development of Training Courses*

Development continues on the following training courses:

- Analyzing Monitoring Data
- Censored Data and Detection Limits
- Interpreting Multivariate Data
- Sampling Designs to Support QA Project Plans
- Introduction to Modeling QA Project Plans
- Assessing Quality Systems
- Data Validation/Verification
- Introduction to QA Project Plans for Modeling
- Introduction to Geospatial Data QA Project Plans
- Statistical Concepts for QA Practitioners.
- Use of Secondary Data Within EPA’s Quality System

5.2 Guidance

Development will continue on the documents listed below.

Projected to be issued in FY04

- Guidance on Data Quality Indicators
- Guidance on Quality Assurance for Environmental Technology Design, Construction, and Operation
- Guidance on Systematic Planning for Environmental Projects
- Guidance on Data Quality Objectives, (5-year update)

- Data Quality Assessment: Statistical Techniques
- Guidance on Data Quality Assessment

Projected to be Peer Reviewed in FY04

- Integrating Systematic Planning and QA Project Plans
- Data Quality Assessment: An Overview
- Guidance on Applying Performance and Acceptance Criteria to Quality Assurance Project Plans

5.3 Assessment of Data Systems

The Quality Staff plans to continue its assessment of EPA's data quality against performance measures developed in FY2001. Analysis and mapping of data systems supporting Agency's decisions will provide insight to data directories, system architecture, reporting hierarchy, standards and business rules, statutory language and rule making documentation. Seven data systems have been mapped to characterize the quality and transparency of the information contained in the databases.

5.4 QMP Review

The Quality Staff expects to review only one QMP that expires in the first quarter of FY05, namely that of NHEERL in ORD.

5.5 Management Assessments

The following organizations will be covered in the next round of reviews:

OSWER: OSRTI, OUST, OBCR, OEPPR, FFRRO
 OEI
 OAR - ORIA, OAP
 OARM - OHROS.
 Regions 8, 7, 9
 OPEI
 OIA

5.6 Workgroup Participation

The Quality Staff anticipates continuing participation in OEI workgroups listed in Section 3.8.